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Summary of Safety and Effectiveness
For the
Precimed Cannulated Screw System

This safety and effectiveness summary for the Precimed Cannulated Screw System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

1. **Submitter:**
Precimed, Inc.
102 Pickering Way, Suite 508
Exton, PA 19341

Contact Person:
Barbara Lyons
102 Pickering Way, Suite 508
Exton, PA 19341

Date Prepared: March 14, 2005

2. Tradename: Precimed Cannulated Screw System
Common Name: Cannulated Screw System
Classification Name: Smooth or threaded metallic bone fixation fastener (888.3040)

3. Predicate or legally marketed devices which are substantially equivalent:

- Cannulated Screw System (S &N Richards)
- Cannulated Screw System (Synthes)

4. Description of the device :

The Precimed Cannulated Screw System is a Cannulated Screw System used for the fixation of bone fractures and for bone reconstructions. It consists of multiple sizes of cannulated screws in varying diameters and lengths.

Materials: The devices are manufactured from 316 LVM stainless steel per ASTM and ISO standards.

Function: The system functions to provide immediate stability and temporary fixation during the natural healing process following fractures.

5. Intended Use:

The Precimed Cannulated Screw System is indicated for use in the treatment of bone fractures, such as fractures of the tarsals and metatarsals, and for metatarsal and phalangeal osteotomies and arthrodeses.

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices :

There are no significant differences between the Precimed Cannulated Screw System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, materials and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 2005

Ms. Barbara Lyons
Precimed Incorporated
102 Pickering Way, Suite 508
Exton, Pennsylvania 19341

Re: K050754
Trade/Device Name: Precimed Cannulated Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: March 14, 2005
Received: March 23, 2005

Dear Ms. Lyons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Precimed Cannulated Screw System

Indications for Use:

The Precimed Cannulated Screw System is indicated for use in the treatment of bone fractures, such as fractures of the tarsals and metatarsals, and for metatarsal and phalangeal osteotomies and arthrodeses.

Prescription Use X___ AND/OR Over-the-counter Use __
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS-LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K050754